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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,362	06/25/2005	Cosimo De Bari	50304/030001	8489

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EXAMINER	
SINGH, ANOOP KUMAR	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,362	DE BARI ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 36-55* is/are pending in the application.

4a) Of the above claim(s) *43-52, 54 and 55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 36-42 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on June 26, 2006, has been received and entered. Claims 2-35 have been canceled, while claims 1, 37-39, 42 have been amended.

Claims 1, 36-55 are pending in the instant application.

Election/Restrictions

Applicant's election of invention of claims 1, 36-42 and 53 (group I) in the reply filed on February 6, 2006 was acknowledged.

Claims 43-52 and 54-55 (groups II and III) were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 6, 2006.

Oath/Declaration

It is noted that the declaration filed on February 6, 2006 in response to restriction requirement under 37 CFR 1.132 was considered as stated in previous office action and therefore no rejection was ever made under 35 U.S.C. 102(a). The declaration was not signed but it has been considered.

Claims 1, 36-42 and 53 are pending.

New-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 36-42 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118(a) states "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case, the recitation of limitation... "wherein said population of muscle progenitor cells is characterized by the absence of the expression of MyoD.." (claim 1) is considered new matter. Applicants point to table 3 and paragraph 138 of the specification for the specific support of the claimed amendment reciting the negative limitation for a population of cells in a composition. However, upon further review of the instant specification, examiner could only find support for human synovial membrane derived muscle progenitor cells showing no MyoD staining. Furthermore, specification provides no link to show that all the mammalian muscle progenitor will be Myo D negative. It is emphasized that this support is directly to composition comprising a population of human muscle progenitor cell derived form joint tissue and not to any mammalian muscle progenitor cell as broadly recited in the claim 1.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981) teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time application was filed...If a claim is amended to include subject matter, limitation or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes, "When

an amendment is filed in reply to an objection or rejection based on U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendment made to the disclosure".

To the extent the claimed compositions are not described in the instant disclosure, claims 1, 36-42 and 53 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since the applicants disclosure do not teach a composition that is adequately described in the specification. In this case, it appears that the claims reflect a genus of mammalian muscle progenitor cell. The claims as amended only have one functional negative characteristics that is these cells do not express MyoD. A review of art would indicate that many cell type do not express MyoD, however, they clearly are not muscle progenitor cells. Simply providing, for what the cell dos not have would constitute an enormous amount of experimentation to empirically test all these cells to determine if they are muscle progenitor cells. As described before, the specification does not provide adequate guidance on determining what is included or excluded by the claims as amended and therefore an artisan of skill would require undue experimentation to practice or make and/or use the invention.

Withdrawn-Claim Rejections - 35 USC § 112

Claims 37-38 and 42 previously rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of amendment in claims 37-38 and 42. However, upon further consideration, a new ground(s) of rejection is made for claim 42.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is vague and indefinite because it is unclear what is encompassed by "the cells retain in vivo myogenic properties after between 3 and 10 passages". The meets and bound of the claim cannot be determined because as recited it is not apparent whether cells are myogenic between 3 and 10 or after 3 and 10 passages. Appropriate correction is required.

Withdrawn-Claim Rejections - 35 USC § 102

Claims 1, 36-39, 41-42 and 53 rejected under 35 U.S.C. 102(b) as being anticipated by De Angelis et al is withdrawn in view of amendment in claim 1. It is noted that De Angelis et al do not teach a composition comprising a population of muscle progenitor cell that is MyoD negative.

Claims 1, 36-39, 41-42 and 53 rejected under 35 U.S.C. 102(a) as being anticipated by Qu-Petersen et al (The Journal of Cell Biology, 2002, 157(5), 851-864) are withdrawn in view of amendment in claim 1. It is noted that De Angelis et al do not teach a composition comprising a population of muscle progenitor cell that is MyoD negative.

New Grounds of Claim Rejection necessitated by Amendment-- 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 36-42 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Chancellor et al (US Patent no 6866842, dated 3/15/2005, effective filing date 5/1/1998, of the record). Claims 1, 36-42 are product by process claims.

Chancellor et al teach a muscle-derived cells, preferably myoblasts and muscle-derived stem cells that is genetically engineered to contain and express one or more heterologous genes for delivery of the encoded gene products at different sites (abstract). In addition, Chancellor discloses a composition comprising muscle derived stem cells that comprises 30-60% cell that are MyoD positive (40-70% negative). Since, composition disclosed by Chancellor comprises a population of Myo D positive and negative cell, which are myogenic in vivo would meet the limitation of claim 1 (see column 38, lines 15-22). Since the composition disclosed by Chancellor and those embraced by the instant claims appear to be structurally same. It will be inherent that cells disclosed by Chancellor would also express other markers as recited in claim 37 and 38. It is noted that Chancellor et al disclose injecting autologous muscle-derived cells (e.g., myoblasts, and muscle-derived stem cells (MDCs)) that have been transfected or transduced with a vector containing at least one gene encoding a growth factor (bFGF, IGF-1, VEGF, PDGF A, B, BMP-2, CDMP) or a neurotropic factor, into a

muscle tissue (col. 9, lines 27-32). Chancellor et al show teach a method of providing population of cell by Myoblast transplantation comprising implantation of myoblast precursors (satellite cells) that enhances muscle regeneration and creates a reservoir of normal myoblasts that can fuse and deliver genes to skeletal muscle (col. 48, lines 42-45). It is also disclosed that intra-articular injection of genetically engineered muscle cells adhered to several structures in the joint, including the ligament, capsule, and synovium. In addition, myoblasts fused to form many post-mitotic myotubes and myofibers at different locations of the newborn rabbit (col. 49, lines 7-16) suggesting these precursor cells are satellite cells. Since, method of independent claim recites only one method step comprising (a) administering a composition of claim 1. Chancellor teaches same method steps as those embraced by the rejected claims. It is noted that Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Accordingly, the invention of claims 1, 36-42 and 53 are anticipated by Chancellor because composition and method steps recited in the invention are the same as those taught by the cited arts.

Claims 1, 36, 38 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznetsov et al (The Journal of Cell Biology, 153(5), 2001, 1133-1139).

Claims 1, 36, 38 and 42 are product by process claims.

Kuznetsov et al teach isolation of adherent, clonogenic cells that phenotypically resemble but are distinguishable from skeletal stem cells found in bone marrow (abstract). It is noted that human fibroblast-like non-osteogenic, human fibroblast-like osteogenic and human marrow stromal cells disclosed by Kuznetsov are characterized by the absence of Myo D expression (see page 1136, table 1). In addition, Kuznetsov et al also teach these cells are clonogenic (see Figure 1, page 1134 and page 1135, column 1, Result and discussion section, paragraph 1). Since, Kuznetsov et al also disclose that these cells with multiple differentiation potential similar to that of post-natal marrow stromal stem cells that can negotiate the circulation. He further emphasize that previous studies have indicated the ability of stromal or other extravascular tissue progenitor cells including myogenic cells to home to their respective peripheral tissues when infused into the circulation. This observation is consistent with the cells disclosed by Kuznetsov et al showing stem cells of extravascular mesodermal tissues exist in the circulating peripheral blood (see page 1138, column 2, paragraph 2). In view of foregoing discussion, it is clear that cells disclosed by Kuznetsov et al that are negative for MyoD and positive for CD44 expression would inherently be cells that would be myogenic and provide consistent pool of satellite cell as disclosed in the claim. Therefore, the composition comprising a population of cells disclosed by Kuznetsov and those embraced by the instant claims appear to be structurally same. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Accordingly, Kuznetsov et al anticipate claims 1, 36, 38 and 42.

Claims 1, 36-38 and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Tamaki et al (J Cell Biol. 2002; 157(4): 571-7 Electronic publication: May 6, 2002).

Claims 1, 36-38 and 41 are product by process claims

Tamaki et al disclose a composition of cell comprising $CD34^+$ cells in the interstitial spaces of skeletal muscles that are characterized by flow cytometry using several cell surface markers (see abstract). It is noted that $CD34^+/45^-$ fraction (SK) of cells soon after isolation are characterized by the presence of c-met and absence of MyoD expression (see figure 4). Since sk-32 fraction of cells disclosed by Tamaki et al are negative for MyoD and positive for c-met expression would inherently be cells that would be myogenic and provide consistent pool of satellite cell as disclosed in the claim. Therefore, the composition comprising a population of cells disclosed by Tamaki et al and those embraced by the instant claims appear to be structurally same. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Accordingly, Tamaki et al anticipate claims 1, 36-38 and 41.

It is noted that all rejections under 102 are for product by process claim. Where, in the instant cases, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness'

under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Further see MPEP § 2113, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Response to Arguments

Chancellor et al (US Patent no 6866842).

Applicant's arguments filed June 26, 2006 have been fully considered but they are not persuasive. Applicants in their argument on page 7, last paragraph state that cell population disclosed by Chancellor are not derived from joint tissue and this is reflected in a physiological difference between the two population of cells as shown by 30-60% of the cells MyoD positive. Applicants assert that the difference in expression of this marker, which is characteristics of myogenic cell and therefore rejection, should be withdrawn (see page 8, first paragraph).

In response, it is emphasized that as recited claim 1 is directed to a composition comprising a population of mammalian progenitor cell. Examiner agree with Applicants argument that Chancellor et al show a composition comprising a population of cell that has 30-60% cell that are Myo D positive. However the same composition comprising population of cell disclosed by Chancellor would also have 40-70% cell that are MyoD negative, which would meet the claim limitation of composition comprising cell of claim

1. Therefore, given the broadest reasonable interpretation and breadth of claimed invention, composition of Anderson would comprise a population of cell that would be MyoD negative. It is also emphasized that the claimed cells and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)) (also see MPEP § 2113).

Withdrawn-Claim Rejections - 35 USC § 103

Applicant's arguments, with respect to the rejection(s) of claims 1, 36-42 and 53 rejected under 35 U.S.C. 103(a) as being unpatentable over De Angelis et al and Chancellor et al have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Chancellor et al (US Patent no 6866842, dated 3/15/2005, effective filing date 5/1/1998) and Tamaki et al (J Cell Biol. 2002; 157(4): 571-7 Electronic publication: May 6, 2002).

New-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 36-42 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamaki et al (J Cell Biol. 2002; 157(4): 571-7 Electronic publication: May 6, 2002) and Chancellor et al (US Patent no 6866842, dated 3/15/2005, effective filing date 5/1/1998).

Claims 1, 36-41 and 53 are product by process claims

Tamaki et al disclose a composition of cell comprising $CD34^+$ cells in the interstitial spaces of skeletal muscles that are characterized by flow cytometry using several cell surface markers (see abstract). It is noted that $CD34^+/45^-$ fraction (SK) of cells soon after isolation are characterized by the presence of c-met and absence of MyoD expression (see figure 4). Since sk-32 fraction of cells disclosed by Tamaki et al that are negative for MyoD and positive for c-met expression would inherently be cells that would be myogenic and provide consistent pool of satellite cell as disclosed in the claim. Therefore, the composition comprising a population of cells disclosed by Tamaki et al and those embraced by the instant claims appear to be structurally same. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. However, Tamaki et al do not explicitly teach do not teach genetically modifying cells with peptide growth factor or angiogenic growth factors

Chancellor et al teach a muscle-derived cells, preferably myoblasts and muscle-derived stem cells that is genetically engineered to contain and express one or more heterologous genes for delivery of the encoded gene products at different sites

(abstract). It is noted that Chancellor et al disclose injecting autologous muscle-derived cells (e.g., myoblasts, and muscle-derived stem cells (MDCs)) that have been transfected or transduced with a vector containing at least one gene encoding a growth factor (bFGF, IGF-1, VEGF, PDGF A, B, BMP-2, CDMP) or a neurotropic factor, into a muscle tissue (col. 9, lines 27-32). Chancellor et al show that Myoblast transplantation comprising implantation of myoblast precursors (satellite cells) enhances muscle regeneration and creates a reservoir of normal myoblasts that can fuse and deliver genes to skeletal muscle (col. 48, lines 42-45). It is also disclosed that intraarticular injection of genetically engineered muscle cells adhered to several structures in the joint, including the ligament, capsule, and synovium. It is emphasized that Chancellor et al teach healing of muscle; meniscal injuries and other muscle related disorder could be improved by cell mediated delivery of exogenous gene for the expression of gene product (Col. 8, lines 7-10; col.8, lines 40-46 and 61-64).

It would have been obvious for one of ordinary skill in the art at the time of invention to modify the composition of Tamaki by genetically modifying the composition by exogenously incorporating nucleic acid encoding growth factor as described by Chancellor. Chancellor et al had already disclosed a muscle-derived stem cells (MDCs) that have been transfected or transduced with a vector containing at least one gene encoding a growth. In addition, Chancellor et al had taught the importance of delivering genetically modified cell for healing meniscal injuries and other muscle related disorder (Col. 8, lines 7-10; col.8, lines 40-46 and 61-64). The skilled artisan would have been motivated to modify the composition of Tamaki to incorporate nucleic acid comprising growth factor as described by Chancellor to improve the healing of muscle injury by delivering cells comprising exogenous genes for the expression of gene product at the injury site.

One who would have practiced the invention would have had reasonable expectation of successfully obtaining a composition comprising a genetically engineered population of mammalian muscle progenitor cell having *in vivo* myogenic activity because Tamaki had already taught a composition comprising Sk-32 progenitor cell having in vivo myogenic property and Chancellor had described the importance of

genetically modifying muscle stem cell composition for the treatment of muscle injuries. One of ordinary skill in art would have been motivated to combine the teaching Tamaki and Chancellor because a composition of progenitor cell comprising a promoter operably linked to a nucleotide sequence encoding a growth factor would have provided a progenitor cell that would have been useful in the treatment for various muscle disorder as taught by Chancellor.

Therefore, the claimed invention would have been prima fascia obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No Claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anoop Singh, Ph.D.
AU 1632